THE HONORABLE MARSHA J. PECHMAN

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

KENNETH McGUIRE, On Behalf of Himself and All Others Similarly Situated, Plaintiffs, v. DENDREON CORPORATION, et al., Defendants.	CASE NO.: C07-800-MJP Consolidated Class Action **DECLARATION OF ERNEST BOGNAR IN SUPPORT OF DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT IN *MCGUIRE V. DENDREON* AND *MOUNTANOS V. DENDREON*** **Note on Motion Calendar: July 30, 2010** **ORAL ARGUMENT REQUESTED**
This document relates to: All Actions.	
WILLIAM MOUNTANOS, PETER MOUNTANOS, JAMES RYE, and TYRONE REMINGA, Plaintiffs, v. DENDREON CORPORATION, a Delaware Corporation, MITCHELL GOLD, and DAVID URDAL, Defendants.	CASE NO.: C09-426-MJP

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I, Ernest Bognar, declare:

1. I am the Senior Director of Facilities & Engineering for Dendreon Corporation ("Dendreon" or "Company"). I make this declaration in support of Defendants' Motion for Partial Summary Judgment in *McGuire v. Dendreon* and *Mountanos v. Dendreon*, filed concurrently herewith. I am familiar with the facts set forth herein and could and would testify thereto if necessary.

2. I have been involved in manufacturing in the biological sciences since 1988, including as Vice President of Manufacturing at Apptec Laboratory Services, Senior Director of Commercial Manufacturing at Imclone Systems Inc., Manager of Manufacturing Processes at Baxter Healthcare, and Production Manager at Cellex Biosciences & Verax.

3. In February 2007, I was the Plant Manager for Dendreon's New Jersey manufacturing facility. In this role, I was part of the management team for the Company's 2007 Pre-License Inspection ("PLI") of the New Jersey facility.

4. I was present throughout the PLI and spoke with Dr. David Urdal, Dendreon's Chief Scientific Officer, at the end of each day of the PLI. We discussed the issues that arose during the inspection each day, and strategized about how to address those issues. After the inspection, Dr. Urdal and I shared our overall satisfaction with the performance of the Dendreon team during the inspection, and our overall thoughts that the inspection was going well.

5. Based on my industry knowledge and prior experience – and the information and expertise shared by other members of the Dendreon leadership team – I knew that it was routine for the FDA to issue a Form 483 following a PLI. For this reason, I fully expected that Dendreon would receive a Form 483 at the conclusion of the inspection, even though we had prepared thoroughly and I thought that the inspection had gone well.

6. My previous industry experience included previous participation in roughly six PLIs and their foreign equivalents. The FDA issued a Form 483 after *each* of these inspections. At the closeout meeting for one of these PLIs (at another company, not Dendreon), the FDA told the company that one of the observations was a "critical finding," and that it was likely it would

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be an obstacle to approval of the product. In my experience, the FDA does not have any reason to pull punches when it is communicating with industry representatives, and if FDA representatives believe that something observed during an inspection will interfere with approval, they will tell you so.

7. I attended the closeout meeting with FDA inspectors at the conclusion of Dendreon's PLI. At this meeting, FDA inspectors reviewed their findings with Dendreon representatives, and told us that we had done a great job in hosting the inspection. There was no indication from any of the FDA representatives that they believed any of the Form 483 observations were "showstoppers" that would prevent FDA approval of the Provenge BLA. To the contrary, I got the impression that the FDA inspectors expected us to submit a timely response to the Form 483 observations, so that they could be resolved in advance of the May 15, 2007 PDUFA date. As a result, I left the FDA closeout meeting feeling very good about the inspection that we had hosted.

8. My opinion that we had hosted a good inspection was confirmed by my independent evaluation of the Form 483 observations, and conversations about these observations with other members of the Dendreon leadership team. Ex. 22 (Form 483). I believed Dendreon could address all of the Form 483 observations in a timely and effective way, so that they would not interfere with approval of Provenge. The Dendreon team had an appropriate and effective response to every observation, and we developed an action plan to resolve each of these observations before the May 15, 2007 PDUFA date.

9. I attended the dinner for Dendreon employees following the PLI, during which the Dendreon team expressed happiness at the successful conclusion of the PLI. Dendreon executives and staff members congratulated one another on all we had accomplished, and there were many toasts to the departments and individuals who had made the PLI a success.

10. Due to much hard work on the part of Dendreon team members, I believe Dendreon did an excellent job hosting the PLI. Other Dendreon executives and staff members expressed similar sentiments to me shortly after the inspection. For example, Dr. Urdal told me

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that he thought the PLI had been a good inspection, and Mary Coon, Dendreon's Vice President of Quality, told me that she thought Dendreon had done a good job. Similarly, I expressed to Dr. Urdal that in my view, the PLI had produced no "showstoppers," and that I was pleased with the outcome of the inspection.

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge. Executed in Morris Plains, NJ, on 6/21/10.

Ernest Bognar

Ernest Bognar

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CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2010, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record who receive CM/ECF notification.

Dated: June 21, 2010

s/ Barry M. Kaplan
Barry M. Kaplan, WSBA#8661

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